K092840

510(k) Summary

510(k) Summary as required by section 807.92(c)

date prepared 10/07/2009

Submission Applicant:

DEC - 3 2009

INSTRUMED INTERNATIONAL, INC.
626 Cooper Court
Schaumburg, IL 60173

Establishment Registration Number:

1421101

Official Correspondent:

Mr. Berndt Fetzer
INSTRUMED INTERNATIONAL, INC.
626 Cooper Court
Schaumburg, IL 60173

Phone: 847-908-0292

Trade name:
Instrumed Forceps Gynaecological

Common name:
Various Gynaecologic specialized manual forceps:
- Gynecological Forceps: Hysterectomy Clamp, Parametrium Clamp, Z-Clamp, Placenta Forceps

Classification name:

21 CFR PART 884 -- OBSTETRICAL AND GYNECOLOGICAL DEVICES
Subpart E--Obstetrical and Gynecological Surgical Devices

Sec. 884.4530 Obstetric-gynecologic specialized manual instrument. Product Code HCZ

Regulation Description

Obstetric-gynecologic specialized manual instrument/forceps

Substantial Equivalence Claims:

HCZ

Preamendment	multiple FORCEPS, SURGICAL, GYNECOLOGICAL Applicant AESCULAP, INC. Specification Developer
Preamendment	Mader Surgical Forceps; Meisterhand Surgical Forceps; Miltex Surgical Forceps; Multiple Surgical Forceps; Sparta Surgical Forceps; Vantage Surgical Forceps Applicant MILTEX, INC. Manufacturer Owner/Operator: INTEGRA LIFESCIENCES CORPORATION

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Description of the Device:

Instrumed gynaecological forceps are heavy forceps which have special designed jaws to hold securely without slipping during vaginal and abdominal hysterectomy procedures, yet do not lacerate the tissue to which it has been applied to even when it is necessary to exert traction.

The Instrumed gynaecological forceps are reusable surgical instruments.

To ensure the multi-purpose use of this device, many different models are available. The differences can be as follows:

- length and bending of the forceps and jaws
- ring handles with a ratchet closure to adjust the amount of tension applied.
- jaw design, option of longitudinal grooves, teeth or cross serrations
- the choice of jaw style depends on the surgeon's preference

The surgeon chooses the gynaecological forceps based on the anatomy of the site and the designs desired are based on the type of the surgical procedure.

Instrumed gynaecological forceps are made of the ASTM F 899-07 standardized Stainless Steel.

The instruments are offered in non-sterile condition.

Indications for Use:

INSTRUMED gynaecological forceps is an instrument with two blades and handles used to pull, grasp, or compress during gynaecological examination.

Comparison with Predicate Device:

The results of non-clinical and bench testing indicates that the new device is completely comparable to the predicate devices. Biocompatibility review and sterilization studies were successfully completed.

The Instrumed product is similiar to the predicate device in terms of technical characteristics, design, Indications for Use, target population, where it is used, performance, biocompatibility, sterilization method, mechanical safety characteristics as well as sizes and configurations. **Therefore it can be deemed substantially equivalent for its indicated use.**

Summary

The presented data that was conducted on the INSTRUMED gynaecological forceps shows in its results and in comparison to the predicate devices that the products are absolutely safe and effective for their intended use and do not raise any new questions regarding safety and effectiveness. The used materials are well researched and do not raise new questions regarding safety and effectiveness of the finished product.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC - 3 2009

Mr. Michael Massong
QA/RA Director
Instrumed International, Inc.
626 Cooper Court
SCHAUMBURG IL 60173

Re: K092840
Trade/Device Name: Instrumed Forceps Gynaecological
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HCZ
Dated: November 10, 2009
Received: November 10, 2009

Dear Mr. Massong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092840

Device Name: Instrumed Forceps Gynaecological

Indications For Use:

INSTRUMED gynaecological forceps is an instrument with two blades and handles used to pull, grasp, or compress during gynaecological examination.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092840